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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/810,611      | 03/29/2004  | Atsushi Suzuki       | 251067US0CONT       | 9751             |

22850 7590 08/18/2006

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EXAMINER

JONES, DWAYNE C

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1614

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/810,611

Applicant(s)

SUZUKI ET AL.

Examiner

Dwayne C. Jones

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01JUN2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,5,7,8 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,11, and 13-19 is/are rejected.
- 7) ☒ Claim(s) 7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 10/161,739.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 4, 5, 7, 8, and 11-19 are pending.
2. Claims 4, 11, 12, and 13-19 are rejected.
3. Claims 7 and 8 are objected.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 11, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following rationale supports this rejection. When the variable of R3 is represented by the group “an amide bond residue”, it is unclear whether the resulting compound is the formation of an amide moiety between the carbonyl group, CO, and a NH group, thus forming an amide bond residue or is there an amide group that bonds to the already present carbonyl group, thus forming an  $\beta$ -ketoamidyl compound. For these reasons, one skilled in the art is not presented with a clear understanding of the meaning and clarity of the term “amide bond residue”, which renders the claim vague and indefinite.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 4 and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 04243822 of 1992 and THE MERCK INDEX. In accordance with MPEP 2131.01, a secondary reference may be cited for a rejection under 35 U.S.C. 102(b) provided it is cited to show an inherent or necessarily present characteristic that is not disclosed by the main or primary reference.

8. JP 04243822 teaches of treating hypertension with caffeic acid as well pharmaceutically acceptable ingredients, such as corn starch, crystalline cellulose, magnesium stearate, (see abstract). THE MERCK INDEX is provided to clearly show that the compound of caffeic acid anticipates the instant claims when R<sup>1</sup> and R<sup>2</sup> are equal to hydrogen.

### *Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 4 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 04243822 of 1992 and THE MERCK INDEX. In accordance with MPEP 2131.01, a secondary reference may be cited for a rejection under 35 U.S.C. 102(b) provided it is cited to show an inherent or necessarily present characteristic that is not disclosed by the main or primary reference.

13. JP 04243822 teaches of treating hypertension with caffeic acid as well pharmaceutically acceptable ingredients, such as corn starch, crystalline cellulose, magnesium stearate, (see abstract). THE MERCK INDEX is provided to clearly show that the compound of caffeic acid anticipates the instant claims when R<sup>1</sup> and R<sup>2</sup> are equal to hydrogen. The determination of a dosage and methods and modes of administration as well as pharmaceutically acceptable carriers, diluents, and excipients having the optimum therapeutic index is well within the level of the skilled artisan. The skilled artisan would be motivated to determine optimum amounts of the drug and methods and modes of administration as well as pharmaceutically acceptable carriers, diluents, and excipients in order to get the maximum effect of the drug while minimizing the adverse and/or unwanted side effects.

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***Allowable Subject Matter***

14. Claims 7 and 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Obviousness-type Double Patenting***

15. The provisional rejection of claims 4, 5, 7, 8, and 11-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-9 and 11-31 of copending Application No. 09/944,079 is removed.

16. The provisional rejection of claims 4, 5, 7, 8, and 11-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-19 and 23-26 of copending Application No. 10/192,075 is removed.

17. The provisional rejection of claims 4, 5, 7, 8, and 11-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 6 of copending Application No. 10/626,708 is removed.

18. The rejection of claims 4, 5, 7, 8, and 11-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-17 of U.S. Patent No. 6,458,392 is removed.

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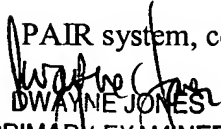
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, may be reached at (571) 272-0718. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

  
DWAYNE JONES  
PRIMARY EXAMINER  
Tech. Ctr. 1614

August 15, 2006